



Indiana University Health

September 6, 2017

U. S. Nuclear Regulatory Commission
Materials Licensing Section
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Dear Sir or Madam:

Indiana University Health Bloomington Hospital would like to amend its Byproduct Materials License, Number 13-10408-02, to add Ramin Hamidi, D.O. as an Authorized User of materials licensed under 10 CFR 35.100, 35.200, and 35.300. Dr. Hamidi was previously listed as an Authorized User on the radioactive materials license of Hillcrest Hospital Cleveland Clinic Health Systems, a copy of which is enclosed.

In addition, we request Per Amundson, M.D. be removed from our license as an Authorized User. Dr. Amundson has discontinued practice at our facility.

If there are any questions concerning this license amendment, please contact the Indiana University Health Bloomington Hospital Radiation Safety Officer, Mr. Patrick J. Byrne, DABR, CHP, DABSNM at 877-317-5811.

Sincerely,

Indiana University Health Bloomington
601 W. Second St.
PO Box 1149
Bloomington, IN 47402
iuhealth.org/bloomington

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OHIO DEPARTMENT OF HEALTH
LICENSE FOR RADIOACTIVE MATERIAL

Pursuant to Chapter 3748 of the Ohio Revised Code, and in reliance on statements and representations made by the licensee, a license is hereby issued authorizing the licensee named herein to receive, acquire, possess, and transfer radioactive material as designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the applications of Chapter 3748 of the Ohio Revised Code and all applicable rules promulgated thereunder. This license is subject to all applicable rules, regulations and orders of the Ohio Department of Health now or hereinafter in effect and to any conditions specified below.

LICENSEE	LICENSE NUMBER
1. Hillcrest Hospital Cleveland Clinic Health Systems	3. 02120180042
2. 6780 Mayfield Road Mayfield Heights, Ohio 44124-2294	EXPIRATION DATE
	4. August 1, 2018
	FILE / ID NUMBER
	5. 501080 / 10684

6. RADIOACTIVE MATERIAL	7. CHEMICAL AND/OR PHYSICAL FORM	8. MAXIMUM QUANTITY THAT LICENSEE MAY POSSESS AT ANY ONE TIME UNDER THIS LICENSE
A. Any radioactive material permitted by rule 3701:1-58-32 of the Ohio Administrative Code	A. Any radiopharmaceutical form	A. As needed
B. Any radioactive material permitted by rule 3701:1-58-34 of the Ohio Administrative Code	B. Any radiopharmaceutical form	B. As needed
C. Any radioactive material permitted by rule 3701:1-58-37 of the Ohio Administrative Code	C. Any radiopharmaceutical form	C. 111 GBq (3 Ci)
D. Iodine -125 permitted by rule 3701:1-58-43 of the Ohio Administrative Code	D. Brachytherapy sealed sources Bard STM 1251 or equivalent	D. 74 GBq (2 Ci)
E. Palladium-103 permitted by rule 3701:1-58-43 of the Ohio Administrative Code	E. Brachytherapy sealed sources IBT Model Optiseed or equivalent	E. 74 GBq (2 Ci)
F. Cesium-131 permitted by rule 3701:1-58-43 of the Ohio Administrative Code	F. Brachytherapy sealed sources Isoray Model CS-1 or equivalent	F. 74 GBq (2 Ci)
G. Iridium-192 permitted by rule 3701:1-58-55 of the Ohio Administrative Code	G. Sealed source (as registered under Elekta Model 105.002)	G. 795.5 GBq (21.5 Ci) total, no single source not to exceed 444 GBq (12 Ci)
H. Yttrium-90 permitted by rule 3701:1-58-72 of the Ohio Administrative Code	H. Sealed sources (TheraSpheres) Y-90 microspheres	H. 111 GBq (3 Ci)
I. Radioactive material permitted by rule 3701:1-58-26 of the Ohio Administrative Code	I. Sealed Sources	I. 37 GBq (1.0 Ci) total, no single source to exceed 1.11 GBq (30 mCi)
J. Yttrium-90	J. Any	J. 4.07 GBq (110 mCi)

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	Amendment Number: 42

9. Authorized Use

- A. Any uptake, dilution, and excretion study permitted by rule 3701:1-58-32 of the Ohio Administrative Code.
- B. Any imaging and localization study permitted by rule 3701:1-58-34 of the Ohio Administrative Code.
- C. Any medical use permitted by rule 3701:1-58-58-37 of the Ohio Administrative Code.
- D-F. Brachytherapy sources for therapeutic medical use permitted by rule 3701:1-58-43 of the Ohio Administrative Code.
- G. For therapeutic medical use permitted by rule 3701:1-58-55 of the Ohio Administrative Code in an Elekta (formerly Nucletron) model 105.999 remote afterloader unit.
- H. For manual permanent brachytherapy implantation therapy as permitted by rule 3701:1-58-72 of the Ohio Administrative Code using TheraSphere Yttrium-90 microspheres and delivery systems.
- I-J. Calibration, transmission and reference sources permitted by rule 3701:1-58-26 of the Ohio Administrative Code.

CONDITIONS

10. Licensed material may only be used at the licensee's facilities located at:

6780 Mayfield Road
Mayfield Heights, Ohio 44124-2294

11. The Radiation Safety Officer for this license is: Leonard A. Kahn, M.D.

12. Licensed material shall be used by, or under the supervision of, individuals designated in writing:

<u>Authorized User</u>	<u>Material and Use</u>
A. Baran, Gregory, M.D.	A. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 of the Ohio Administrative Code
B. Blair, Henry, M.D.	B. Uses permitted by rules 3701:1-58-43, 3701:1-58-55 limited to Iridium-192 in a HDR device, and rule 3701:1-58-72 limited to Yttrium-90 TheraSpheres (IN-VITRO STATUS - License condition 16) of the Ohio Administrative Code
C. Brown, David W., M.D.	C. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 of the Ohio Administrative Code
D. Brunken, Richard C., M.D.	D. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 of the Ohio Administrative Code
E. Cerqueira, Manuel, M.D.	E. Uses permitted by rules 3701:1-58-32 and 3701:1-58-34 of the Ohio Administrative Code
F. Chan, Vincent, M.D.	F. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 of the Ohio Administrative Code
G. Christian, Michael O., M.D.	G. Uses permitted by rules 3701:1-58-32 and 3701:1-58-34 of the Ohio Administrative Code
H. Ciezki, Jay, M.D.	H. Uses permitted by rules 3701:1-58-37 and 3701:1-58-43 of the Ohio Administrative Code
I. Haddadin, Ihab, M.D.	I. Use permitted by rule 3701:1-58-72 limited to Yttrium-90 TheraSpheres (IN-VITRO STATUS - License condition 16) of the Ohio Administrative Code
J. Hamidi, Ramin, D.O.	J. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 of the Ohio Administrative Code
K. Hughes, Lisa, M.D.	K. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 of the Ohio Administrative Code
L. Kahn, Leonard A., M.D.	L. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 of the Ohio Administrative Code

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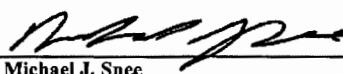
<u>Authorized User</u>	<u>Material and Use</u>
M. Kwok, Pauline, M.D.	M. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 of the Ohio Administrative Code
N. Mastroianni, Anthony, M.D.	N. Uses permitted by rules 3701:1-58-43 and 3701:1-58-55 (limited to Iridium-192 in a HDR device) of the Ohio Administrative Code
O. Neumann, Donald R., M.D., Ph.D.	O. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 of the Ohio Administrative Code
P. Nunez-Hoyo, Marisol, M.D.	P. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 of the Ohio Administrative Code
Q. Obi, Betty B., M.D.	Q. Uses permitted by rules 3701:1-58-43 and 3701:1-58-55 (limited to Iridium-192 in a HDR device) of the Ohio Administrative Code
R. Purysko, Andrei, M.D.	R. Uses permitted by rules 3701:1-58-32, 3701:1-58-34, and 3701:1-58-37 (limited to the oral administration of sodium iodide Iodine-131) of the Ohio Administrative Code
S. Saks, John, M.D.	S. Uses permitted by rules 3701:1-58-32 and 3701:1-58-34 of the Ohio Administrative Code
T. Shrikanthan, Sankaran, M.D.	T. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 of the Ohio Administrative Code
U. Stephens, Kevin, M.D.	U. Uses permitted by rules 3701:1-58-43 and 3701:1-58-55 (limited to Iridium-192 in a HDR device) of the Ohio Administrative Code
V. Tendulkar, Rahul, M.D.	V. Uses permitted by rules 3701:1-58-37 (limited to parental administrations for which a written directive is required), 3701:1-58-43 and 3701:1-58-55 (limited to Iridium-192 in a HDR device)
W. Thomas, Afu, M.D.	W. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 of the Ohio Administrative Code
X. Vermont, Carmen, M.D.	X. Uses permitted by rules 3701:1-58-43 and 3701:1-58-55 (limited to Iridium-192 in a HDR device) of the Ohio Administrative Code
Y. Wu, Guiyun, M.D.	Y. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 of the Ohio Administrative Code

<u>Authorized Medical Physicists</u>	<u>Material and Use</u>
A. Kolar, Matthew, M.S.	A. Iridium-192 for use in a High Dose Rate Remote Afterloader Unit
B. Qi, Ping, Ph.D.	B. Iridium-192 for use in a High Dose Rate Remote Afterloader Unit
C. Rybak, Maria, M.S.	C. Iridium-192 for use in a High Dose Rate Remote Afterloader Unit
D. Strongosky, Mike, M.S.	D. Iridium-192 for use in a High Dose Rate Remote Afterloader Unit
E. Wilkinson, Allan, Ph.D.	F. Iridium-192 for use in a High Dose Rate Remote Afterloader Unit
13. All persons performing activities meeting the definition of "Nuclear Medicine Technologist" as specified in R.C. 4773.01 shall be licensed and in good standing with the State of Ohio.	
14. Notwithstanding the possession limits in item 8, the licensee shall further restrict the possession of licensed materials to quantities below the minimum limit specified in rule 3701:1-40-17 of the Ohio Administrative Code, for establishing decommissioning financial assurance.	

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15. In accordance with the requirements of rule 3701:1-58-30 of the Ohio Administrative Code, any patient administered gamma emitting radiopharmaceuticals or permanent brachytherapy sources shall be provided a patient release card to include:
- 1) The patient's name.
 - 2) The radionuclide administered and its activity.
 - 3) The facility name which administered the radionuclide.
 - 4) The date of the administration of the radionuclide.
 - 5) The expiration date of the card.
- The card is not applicable to those patients who are institutionalized (Hospitals, Nursing Homes, Correctional Institutions, etc.) or whose radiation levels do not exceed 0.1 mR/hr at one meter.
16. The (IN- VITRO STATUS) Authorized User for Yttrium-90 TheraSphere microspheres shall complete the first three hands-on patient cases supervised in the physical presence of a manufacturer representative. The licensee must submit documentation within 30 days of when these three patient cases have been completed to the Bureau of Radiation Protection in a formal amendment request. After receiving the appropriate documentation, an amendment will be issued removing the (IN-VITRO STATUS) of the Authorized User.
17. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Ohio Department of Health's statutes, rules, and orders shall govern unless statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Renewal application dated April 10, 2013
 - B. Electronic correspondences dated May 30, 2013; License 02120180042 renewed its entirety
 - C. Letter dated April 21, 2014 (Amendment 39)
 - D. Electronic correspondence dated July 23, 2014 (Amendment 40)
 - E. Letter dated April 6, 2015 and correspondence dated April 7, 2015 (Amendment 41)
 - F. Letter dated August 19, 2015 (Amendment 42)

For the Ohio Department of Health

DATE: 9/15/15 BY: 
 Michael J. Snee
 Bureau of Environmental Health and Radiation Protection
 on behalf of the Director of Health



Indiana University Health

Indiana University Health Bloomington
PO Box 1149
Bloomington, IN 47402

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U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSING SECTION

2443 WARRENVILLE ROAD, SUITE 210

LISLE, IL 60532-4352

41 HRDPMSB 60532

